

## REMARKS

Amendments have been made to respond to the issues and concerns raised in the Office Action, to clarify aspects in the specification and claims, and to refine claim language. The amendments are believed to be consistent with the disclosure originally filed. The amendments also have been particularly presented to avoid, where applicable, any admission or estoppel, generally, negatively affecting the scope of protection provided by the disclosure and claims of the present application, and also in a manner that avoids prosecution history estoppel, limitation of the scope of equivalences, or the like. Any amendment should not be construed as an admission regarding the propriety of any objection or rejection raised in any Office Action, and the Applicant reserves the right to pursue the full scope of the unamended claims in any subsequent patent application as may be appropriate.

Claims 1-123 and 142-143 have been cancelled. Claims 124-141 remain in the application. Each amendment is believed to have been made in accordance with Rule 121. However, should any unintended informality exist, it is requested that the undersigned be contacted by telephone so that it may be resolved as expediently as possible. It is believed the amendments fully respond to the issues raised in the Office Action. Further detail with respect to specific points raised in the Office Action is offered below.

The Office raises a new matter concern with respect to the use of sorted versus unsorted sperm. The Applicant disagrees that this issue poses a new matter concern. Attached to this response as Exhibit "A" is a declaration from David G. Cran, an expert in the field of animal reproduction. As stated in the declaration, it is well known to those having skill in this art that sorted sperm is more difficult to achieve successful fertilization with than unsorted sperm. This is because use of sorted sperm requires additional steps *vis-à-vis* unsorted sperm tending to complicate the artificial insemination process and reduce the efficacy of the sperm. For this reason, fertilization success rates achieved when using sorted sperm may be presumed to hold also for the same procedure

carried out with unsorted sperm. Of course, use of unsorted sperm will not yield sex ratios with the accuracy of sorted sperm. However, the issue of sex ratio is separate and distinct from simple fertilization success. In this manner, fertilization success rates for the example on pages 22-23 of the specification may be presumed valid for both sorted and unsorted sperm, and no new matter concerns are implicated.

The Office raises various new matter concerns with respect to the method of Applicant's claims as recited. The Applicant disagrees that the recitations of the claims pose a new matter issue. Each recitation of independent claim 124 is expressly supported by the example on pages 22-23 of the specification. Accordingly, the example demonstrates that the Applicant possessed the subject matter of the method of the claims as recited as of the filing of the application, and no new matter concerns are implicated.

The Office raises a new matter concern regarding comparison to the fertilization success rates cited in the Seidel (1997) reference. The Applicant disagrees that such comparison to the Seidel (1997) reference poses a new matter issue.

First, the Office in its previous Office Action dated November 24, 2006 expressly stated that it considered the use as described in the Seidel (1997) reference of  $2.5 \times 10^6$  sperm as a typical dosage to achieve pregnancy rates of 62% and 50%. This statement by the Office was used to make substantive rejections of the Applicant's claims, and the Applicant was required to substantively respond to the same. Because the Office previously has conceded the use of the Seidel (1997) reference, and in fact used this reference in rejections of the Applicant's claims, the Office cannot now argue the opposite position that comparison to this data is not permitted.

Second, the Seidel (1997) reference on its face teaches the use of  $2.5 \times 10^6$  sperm for artificial insemination. This sperm number constitutes a "typical unsorted insemination dosage" as recited by the claims. In particular, the specification at page 19 sets forth a numerical range expressly stated to encompass the numbers of sperm considered to be typical for the artificial insemination of bovines, to wit, "Typical

artificial insemination is presently conducted with millions of sperm for bovine species... For bovine sperm where currently 1 to 10 million sperm are provided..." The declaration of David G. Cran, attached to this response as Exhibit "A", further makes clear that one of skill in this art would understand this disclosure of the specification as teaching that the range of 1 million to 10 million encompasses the number of sperm considered to be a "typical insemination dosage" for bovines. Because the  $2.5 \times 10^6$  number constitutes a "typical insemination dosage" as recited by the claims, it is appropriate to take note of the fertilization success rates achieved for this number of sperm in the Seidel (1997) reference and compare them with those of Applicant's example on pages 22-23 of the specification. Accordingly, comparison to the Seidel (1997) reference implicates no new matter concerns.

The Office states that the information in the Seidel (1997) reference is essential material and therefore cannot be incorporated by reference, since the Seidel (1997) reference is a non-patent publication. The Applicant disagrees that the information in the Seidel (1997) reference is essential material. With reference to 37 C.F.R. § 1.57, the information in the Seidel (1997) reference is not required to support written description, enablement, or best mode concerns under 35 U.S.C. 112(1), definiteness concerns under 35 U.S.C. 112(2), or a "means for" recitation in the claims under 35 U.S.C. 112(6). This information is all present in the specification as filed, for instance in the example on pages 22-23. Rather, the Seidel (1997) reference simply provides additional evidence, by way of comparison, that confirms these teachings of the specification. In this manner, the information in the Seidel (1997) reference is not essential material. However, to simplify the examination procedure, the Applicant has amended the specification to include the relevant portions of the Seidel (1997) reference pursuant to 37 C.F.R. § 1.57, MPEP § 608.01(p), and MPEP § 2163.07(b). The material being inserted is the material previously incorporated by reference, and the amendment contains no new matter.

The Office raises a new matter concern regarding criteria for ascertaining whether the specification as originally filed contemplated the fertilization success rates recited in the claims. The Applicant disagrees that the claimed fertilization success rates raise such

a new matter issue. The Office appears to concede in the Office Action that the example on pages 22-23 of the specification yields a fertilization success rate of 121% or 150% as compared to the fertilization success rates of the Seidel (1997) reference, and that these percentages fall within the range claimed by the Applicant.<sup>1</sup> In this manner, the Applicant believes the claimed success rates are consistent with the disclosure of the specification as originally filed, demonstrating possession of this subject matter and implicating no new matter issues. If the Office believes different criteria are applicable, the Applicant respectfully requests the Office to explicitly state these criteria so that the Applicant may have the requisite information to further consider the issue.

The Office raises an enablement concern with respect to the fertilization success rates achieved on pages 22-23 of the specification. The Applicant disagrees these fertilization success rates pose an enablement issue.

First, with regard to the Office's contention that embryos were recovered from 9 of 12 heifers and that no indication is given concerning whether ova from the remaining three heifers were fertilized, the Applicant notes that the only way data from the remaining three heifers could change the disclosed fertilization success rates would be by way of improvement. In particular, if no ova from the remaining three heifers were fertilized, then the disclosed fertilization success levels would be unchanged, and if any ova from the remaining three heifers were fertilized, then the disclosed fertilization success levels would be improved. Consequently, the fact that the status of ova from the remaining three heifers is not stated cannot hurt the fertilization success levels claimed by the Applicant, and indeed could potentially improve them. Regardless, the data from the 9 heifers from which ova and embryos were collected is sufficient to support the Applicant's claimed fertilization success levels.

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<sup>1</sup> The Applicant notes it is revising these percentages to 110% and 136% respectively, as discussed elsewhere herein with respect to the enablement issue raised by the Office regarding the fertilization success rates achieved on pages 22-23 of the specification. However, the Applicant notes that even these lower percentages fall within the range claimed by the Applicant and therefore do not change the substance of the Applicant's points here. Accordingly, the Applicant has used the 121% and 150% figures here to simplify the discussion and keep the figures consistent with those stated by the Office in the prior Office Action.

Second, the Applicant disagrees with the Office's contention that the disclosure that 52 of 96 (54%) ova produced embryos at normal stages of development or that 65 of 96 (68%) ova were fertilized does not clearly state the fertilization success levels achieved relative to a typical unsorted insemination dose. If the Office's point is that it is unclear how many ova were successfully fertilized, then the Applicant notes the Office appears to concede that 68% of ova were successfully fertilized. If the Office's point is that it is unclear what a typical unsorted insemination dose is, then the Applicant notes that the results of Seidel (1997) support this comparison, as discussed elsewhere herein. In particular, the 68% fertilization success rate of the example on pages 22-23 of the specification is equal to 110% of the 62% pregnancy rate in Seidel (1997) ( $0.68 / 0.62 = 1.10$ ), and the 68% fertilization success rate of the example on pages 22-23 of the specification is equal to 136% of the 50% pregnancy rate in Seidel (1997) ( $0.68 / 0.50 = 1.36$ ).

Third, attached to this response as Exhibit "A" is a declaration from David G. Cran, an expert in the field of animal reproduction. The declaration provides further evidence that one skilled in this art would understand the example on pages 22-23 of the specification as teaching a 68% fertilization rate.

The Office raises various enablement concerns with respect to the method of Applicant's claims as recited. The Applicant disagrees that the recitations of the claims pose any enablement issues. Each recitation of independent claim 124 is expressly supported by the example on pages 22-23 of the specification. Accordingly, the example provides all information necessary for one skilled in the art to practice the method of the claims as recited, and no enablement concerns are implicated. Moreover, the Applicant has attached to this response as Exhibit "B" publications by Dieleman, Hasler, Iwazumi, and Mapletoft demonstrating that superovulation protocols are well known in the art. As stated in MPEP § 2164.08, "Claims are not rejected as broader than the enabling disclosure under 35 U.S.C. § 112 for noninclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and

claims are directed would consider them obvious.” The publications provide evidence that superovulation procedures are known in the art, and therefore specific protocols need not be recited in the Applicant’s claims. Accordingly, no enablement issues are implicated by the claims.

## CONCLUSION

Having addressed each of the concerns raised in the Office Action, the Applicant respectfully requests reconsideration and withdrawal of the rejections and objections to the application. Allowance of claims 124-141 is requested at the Office's earliest convenience.

Dated this 13<sup>th</sup> day of February, 2008.

Respectfully submitted,  
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**EXHIBIT A TO RESPONSE**